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10/785,207	02/24/2004	Shanta Modak	070050.2534	8835
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/785,207	Applicant(s) MODAK ET AL.	
	Examiner ALI SOROUGH	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 14,15,17,18,21 and 23-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13,16,19,20,22,33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed 02/19/2008 to the Office Action mailed on 11/19/2007 is acknowledged.

Status of the Claims

Claims 14, 15, 17, 18, 21, and 23-32 are withdrawn and claims 1, 7-13, 19, 20, and 34 are currently amended. Therefore, claims 1-13, 16, 19, 20, 22, 33, and 34 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1, 2, 3, 5-10, 12, 13, 16, 19, 20, and 22 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-11, and 17 of copending Application No. 10/622272 **is maintained**.

Response to Applicant's Arguments

Applicant argues that since the overlapping claims have not yet been patented Applicants will agree to submit a terminal disclaimer at such necessary time. Therefore, the instant rejection of claims 1, 2, 3, 5-10, 12, 13, 16, 19, 20, and 22 on the ground of nonstatutory obviousness-type double patenting is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear if applicant intends to incorporate octoxyglycerin as an emollient solvent into independent claim 1 since dependent claim 11 is directed to ethyl hexyl

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glycerin (octoxyglycerin). Therefore, it is not clear if applicant claims octoxyglycerin present twice in the instant composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 4, 6-8, 11, 19, 20, 22, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US Patent 5110809, Published 05/05/1992) in view of Cupferman et al. (US Patent 6040347, Published 03/21/2000).

Applicant Claims

Applicant claims a composition comprising alcohol, water, hydrogel, and an emollient.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Wang et al. teaches an antifungal gel formulation comprising 0.2 to 2.0 % imidazole antifungal agent, 0.01-2.5% 17-ester, steroid, 30-60% lower alcohol, 0-45% dihydroxy alcohol, 0-40% trihydroxy alcohol, 0.1-5% gelling agent, 0-20% water, 0-30% emollient, 0-2.0% fragrance, and 0-1.5% preservative. The emollient can be PPG-20 methyl glucose ether (Glucam P-20), the gelling agent is most preferably hydroxypropyl cellulose or hydroxyethyl cellulose, and the lower alcohol is ethanol. (See title, column 8, Lines 1-3, Lines 10-24, Lines 29-31, and Line 54).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Wang et al. does not anticipate the instant concentrations, hydroxyethyl cellulose as the hydrogel, and Glucam P-20 as the emollient. However, Wang et al. makes instantly claimed invention obvious.

Wang et al. further lacks a composition comprising octoxyglycerin. This deficiency is cured by the teachings of Cupferman et al.

Cupferman et al. teaches a treatment gel for seborrheic skin comprising 5% octoxyglycerol, 1% xanthan gum, 2% glycerol, 0.2% fragrance, 30% ethyl alcohol, 1% cosolvent, and the remaining demineralized water. (See column 6, example 4). Octoxyglycerol is useful in acting against pathologies related to *Propionibacterium acnes* and *Propionibacterium granulosum*, and in particular to treat seborrhea and acne. (See column 1, Lines 62-64).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention to adjust the concentrations of the composition taught by Wang et al. to arrive at the instantly claimed concentrations. One would have been motivated to use hydroxyethyl cellulose as the gelling agent because Wang et al. teaches that such a compound is a preferably gelling agent. One would have been motivated to use Glucam P-20 as an emollient because Wang et al. teaches that such a compound could be used in the formulation taught by Wang et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Wang et al. with Cupferman et al. One would have been motivated to do so because the addition of octoxyglycerol to the gel composition Wang et al. would add further antimicrobial activity. For the foregoing reasons the instant invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

2. Claims 1-6, 13, 16 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaussee (US Patent 4478853, Published 10/23/1984) in view of Cupferman et al. (US Patent 6040347, Published 03/21/2000).

Applicant Claims

Applicant claims a composition comprising alcohol, water, hydrogel, and an emollient.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Chaussee teaches a composition comprising 48.0% ethanol, 1.0 dimethicone (silicone polymer), 1.0% cyclomethicone (silicone polymer), 0.3% carbopal 940

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(hydrogel), 3.0% glycerol (emollient), 42.29% deionized water, 0.16 % triethanolamine (thickening agent), and other components. The silicone polymers may optionally be present in the composition in amount preferably from 1 to 3%. The composition may further include a topical antiseptic such as bezalkonium chloride. The composition may also further comprise preferably from 1 to 10 % of an emulsifier. (See column 10, Lines 45-59, column 8, Lines 16-31, column 4, Lines 48-56).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Chaussee does not anticipate a composition comprising from 0.1 to 1% silicone polymer and does not anticipate a composition comprising bezalkonium chloride.

However, Chaussee makes such a composition obvious.

Chaussee further lacks a composition comprising octoxyglycerin. This deficiency is cured by the teachings of Cupferman et al.

Cupferman et al. teaches a treatment gel for seborrheic skin comprising 5% octoxyglycerol, 1% xanthan gum, 2% glycerol, 0.2% fragrance, 30% ethyl alcohol, 1% cosolvent, and the remaining demineralized water. (See column 6, example 4).

Octoxyglycerol is useful in acting against pathologies related to *Propionibacterium acnes* and *Propionibacterium granulosum*, and in particular to treat seborrhea and acne. (See column 1, Lines 62-64).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention to adjust the concentrations of silicone polymer to the instantly claimed concentration because Chaussee teaches that the concentration can be preferably as low as 1% which is within the instantly claimed concentration range. One would have been motivated to add benzalkonium chloride to the composition taught by Chaussee because Chaussee teaches that such a compound can be advantageously added to the composition.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Chausee with Cupferman et al. One would have been motivated to do so because the addition of octoxyglycerol to the gel composition Chausee would add further antimicrobial activity. For the foregoing reasons the instant invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

3. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chaussee (US Patent 4478853, Published 10/23/1984) in view of Cupferman et al. (US Patent 6040347, Published 03/21/2000) further in view of Hahn et al. (US Patent 5804203, Published 09/08/1998).

Applicant Claims

Applicant claims a composition comprising alcohol, water, hydrogel, and an emollient.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The combined teachings of Chausee and Cupferman et al. are disclosed above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Chaussee and Cupferman et al. do not disclose a composition comprising Incroquat Behenyl TMS-50 as the emulsifier. This deficiency is cured by the teachings of Han et al.

Hahn et al. teaches topical formulation for containing strontium for reducing skin irritation. The composition includes emulsifiers including Incroquat Behenyl TMS. (See title and column 18, Lines 27-29).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention to combine the teachings of Chaussee and Cupferman et al. with Hahn et al. One would have been motivated to add Incroquat Behenyl TMS to the composition taught by Chaussee because Chaussee teaches that such a emulsifier can be advantageously added to the composition. For the foregoing reasons the instant invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chaussee (US Patent 4478853, Published 10/23/1984) in view of Cupferman et al. (US Patent 6040347, Published 03/21/2000) further in view of Wivell et al. (US Patent 5599549, Published 02/04/1997).

Applicant Claims

Applicant claims a composition comprising alcohol, water, hydrogel, and an emollient.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The combined teachings of Chaussee and Cupferman et al. are disclosed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Chaussee and Cupferman et al. do not disclose a composition comprising dimethiconol fluid in dimethicone as the silicone polymer. This deficiency is cured by the teachings of Wivell et al.

Wivell et al. teaches a personal cleansing and moisturizing compositions. The compositions comprise as a moisturizing component silicones such as dimethylpolysiloxane, diethylpolysiloxane, and dimethicone in volatile cyclomethicone fluid as a carrier. (See title, column 4, Lines 65-67 and column 5, Lines 1-11).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention to combine the teachings of Chaussee and Cupferman et al. with Wivell et al. One would have been motivated to dimethicone in volatile cyclomethicone fluid to the composition taught by Chaussee because Chaussee teaches that such a silicone polymer can be advantageously added to the composition. For the foregoing reasons the instant invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent

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Ali Soroush
Patent Examiner
Art Unit: 1616

/Mina Haghighatian/

Primary Examiner
Art Unit 1616